REMARKS

Applicants confirm the previous election of the group 1 invention, but note that the examiner has modified the group 1 invention to include claims 24 and 25. Non-elected claims 26-31 have been canceled without prejudice or disclaimer. Applicants expressly reserve their rights to file one or more divisional application(s) directed to the non-elected subject matter, claiming the benefits afforded by 35 U.S.C. 119, 120 and 121.

Reconsideration of the previous rejections under 35 U.S.C. 112, second paragraph, are respectfully requested.

Claim 1 and dependant claims stand rejected under 35 U.S.C. 112 second paragraph allegedly as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully submit that claim 1 and the claims dependant thereon do specifically particularly point out and distinctly claim the subject matter which applicants regard as the invention.

For example, independent claim 1 recites polybasic acid, which is the subject matter that applicants regard as their invention.

The Examiner wants to redefine the subject matter that applicants regard as the invention as being to only specific polybasic acids.

However, applicants respectfully point that Congress has granted the exclusive right to define the subject matter that applicants regard as the invention to applicants and only to applicants. In this regard, applicants respectfully direct the Examiner's attention to In re Borkowski, 164 USPQ642, 645 (CCPA 1970) in which the court stated, "The examiner's approach to determining whether appellants' claims satisfy the requirements of §112 appears to have been to study appellants' disclosure, to formulate a conclusion as to what he (the

Examiner) regards as the broadest invention supported by the disclosure, and then to determine whether appellants' claims are broader than the Examiner's conception of what 'the invention is'. We cannot agree that § 112 permits such an approach to claims".

The Examiner is also mistaken in his understanding that "the pH of the extracting solution is an essential element in the process of purification". Similarly, the Examiner's statement that "further confusing the recitation of "strength" of the polybasic acid, in a manner unusual in the art".

A simple internet sheet search on the term "acid strength" will yield many definitions of "acid strength" which are not based on pH. Rather, the strength of acids ("and bases") is based on a degree of ionization or dissociation insofar that all acids ("and bases") are not of equal strength in producing H+ ("and OH-") ions in solution. The terms "strong" (and "weak") give an indication of the strength of an acid (or base). The term "strong" (and "weak") describe the ability of an acid (and base) solutions to conduct electricity. If the acid (or base) conducts electricity strongly, it is a strong acid (or base). If the acid (or base) conducts electricity weakly, it is a weak acid (or base). Thus the Examiner is confusing the term "acid strength" with pH, which are different terms used for different purposes. Accordingly, the Examiner's entire attempt at recasting the invention into what he (the Examiner) thinks the invention is is the sole reason for the rejection under 35 U.S.C. 112, second paragraph, a proposition which the courts have clearly rejected. Accordingly, withdrawal of the rejection of the claims under 35 U.S.C 112, second paragraph, is respectfully requested.

Reconsideration of the rejection of claim 1 and claims dependant thereon under 35 U.S.C. 112, 1st paragraph is also respectfully requested.

Although the Examiner acknowledges that the specification, is "enabling for the purification of citalopram under well defined conditions using one

polybasic acid or salt at one specific concentration". Further, it is alleged that the specification does not reasonably provide enablement for obtaining pure citalopram from "crude mixture" of citalopram prepared by any method using any polybasic acid. Again, the Examiner is attempting to recast applicant's claimed invention into a style fitting the format of the rejection, but having little to do with the claimed invention.

Firstly, the applicant's process of claim 1 is not any method but provides a crude mixture comprising citalopram...dissolved in a water immiscible organic solvent, including one or more citalopram derivatives which are present as citalopram impurities. Moreover, the claimed invention does not obtain pure citalopram "by any method using any polybasic acid". Rather, the claimed invention specifically recites that the crude mixture...dissolved in a water immissible organic solvent is washed with at least one dilute aqueous solution of a polybasic acid so as to separate some of said citalopram from citalopram impurities wherein the polybasic acid is present in solution in a strength of 0.5 to 6%. While the Examiner surmises that other polybasic acids, such as citric acid, would not work in the present invention, he does not consider all the limitations of the claim i.e. the solution having the strength in the range of 0.5 to 6% as instantly recited. The claimed polybasic acid, present in solution in a strength, as recited, is conceded to be supported by the specification and thus enabled. However, if polybasic acids are not available in such strength, then, of course, they are excluded from the claimed invention, and the Examiner is mistaken in concentrating only on one term of the claimed invention without considering the invention as a whole as specifically claimed. Applicants have not only exemplified the used of polybasic acids which satisfy the claimed invention but other polybasic acids which fall within the metes and bounds of the claimed invention can be utilized without undue experimentation in order to achieve the results of the claimed invention. Accordingly, applicants respectfully submit the

instant specification is enabled for purifying citalopram, not only for the specific polybasic acid, disodium edetate, but also for others falling with the limitations of the claimed invention.

It is noted in passing that the Examiner confuses the Examples. In comparing working Example 2 in which the crude solution containing citalopram is, in the second washing step, washed with 5% disodium edetate but the Examiner should note that in the first washing step, the polybasic acid has an acid strength of 1. Note this difference which is more explicitly exemplified in Example 2 in which the step of using 5% disodium edetate solution is the second washing step (see lines 10-11 of paragraph [0053]) whereas the first washing step uses disodium acetate solution having a strength of 1% (see lines 9-10 of paragraph [0053]) as compared to Example 1, in which only a single washing step is exemplified. In this regard, applicants again respectfully direct the Examiner's attention to the specification and specifically the explanation of the two washing steps and their purpose as set forth in paragraphs [0035] and [0036] of the specification. The Examiner apparently uses these examples to substantiate his argument that the efficiency of the yield is not disclosed. Applicants respectfully direct the Examiner's attention to the fact that independent claim 1 does not recite the efficiency of the yield and thus there is no need to have enablement for a feature which is not the claimed invention. Again the Examiner is attempting to recast the subject matter of the invention as something that is other than what applicants regard as their invention and then makes the argument that that the specification is not enabled for such recast subject matter. However, if the Examiner would properly conduct his examination in compliance with the patent statutes, especially 35 U.S.C. 112, second paragraph, and then conduct his examination of the specifically claimed subject matter it would then be clear to the Examiner that the claims are enabled for the claimed subject matter and not for subject matter which applicant has not

claimed and therefore for which the specification does not have to provide an enabling disclosure. Withdrawal of all rejections under 35 U.S.C. 112, first paragraph are therefore respectfully requested.

Reconsideration and withdrawal of the previous rejection of claim 1 and claims dependent thereon under 35 U.S.C. 103(a) as being unpatentable over Coppi et al. ("USP 6,635,773") and Satyanarayana et al. ("GB 2375763 A") is respectfully requested.

It is the Examiner's initial burden to establish a factual basis for all rejections under 35 U.S.C. 103 (obviousness) and "may not because of the doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis, In re Warner, 379 F.2d 1011, 1017 (CCPA 1967). While the Examiner has cited the combination of Coppi et al. and Satyanarayana et al., the Examiner has conceded (page 6, lines 4-6 of the Office Action) that such combination "do not teach the limitations of the instant claim such as the use of polybasic acid and/or the range of the "strength" of the acid for washing organic solutions as instantly claimed.

Thus, the Examiner has not satisfied his initial burden of establishing a factual basis for the rejection under 35 U.S.C. 103 (a).

Coppi discloses a process which fundamentally works in a different way to the claim process: Coppi discloses a process which involves isolation of citalopram base in the form of an oil, whereas, in the present invention, the citalopram free base is always in solution; see the express limitations of claim 1 of the claimed invention.

Thus, compared to the Coppi process, the process of the present invention is simpler and reduces the number of isolation steps required which, in

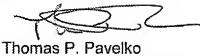
turn, increases yield, and the suitability for an industrial scale-up procedure.

On the other hand, Satyanarayana is acknowledged in the description of the present invention. Like the Coppi process, the Satyanarayana process fundamentally works in a different way from the claimed process: Satyanarayana disclose a process which involves isolation of citalopram base in the form of an oil, whereas, in the present invention, the citalopram free base is always in solution. Furthermore, there are numerous salt formation and basification steps in the Satyanarayana process (as acknowledged by the Examiner). Therefore, the Satyanarayana process suffers from a major disadvantage, in that the purification process has to be repeated a number of times, or it is necessary to be employed in conjunction with other methods, to obtain citalopram of acceptable pharmaceutical grade. Not only is the Satyanarayana process lengthy, tedious but is not suitable for industrial scale manufacturer of citalopram.

As to the Examiner's alleged "motivation" to modify the extraction process with alternate acid to adjust the pH and temperature for extractions such would not produce a reasonable expectation of success, because both the Coppi and Satyanarayana processes involve isolation of citalopram based on the form of an oil, whereas in the claimed invention, the citalopram free base is always in solution. Thus, unlikely citation of In re Aller, 105 USPQ 233, 235 (CCPA 1955), the Examiner's supposed "motivation" still does not disclose the conditions necessary to achieve the claimed invention even if one were to use alternate acids, adjust the pH and temperature as suggested by the Examiner. Accordingly, applicants respectfully submit that the Examiner has not even attempted to carry his burden of establishing a prima facie case of obviousness for the claimed invention and therefore withdrawal of the rejection is respectfully requested.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 14-1437, under Order No. 8693.016.US0000.

Respectfully submitted,



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